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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/896,096      | 06/28/2001  | Avi J. Ashkenazi     | P1134R2C2           | 3212             |

9157 7590 09/23/2002

GENENTECH, INC.  
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

KAUFMAN, CLAIRE M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 09/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/896,096

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/28/01, 8/13/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30-39 and 67-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-39 and 85-89 is/are allowed.
- 6) ☒ Claim(s) 67-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>6</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6</u> . | 6) <input type="checkbox"/> Other:   |

### DETAILED ACTION

The preliminary amendments filed June 28, 2001, and August 18, 2001, have been entered.

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#### *Specification*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Antibodies to DcR3 Polypeptide, a TNFR homolog .

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#### *Priority*

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). While the instant application claims benefit to provisional applications in the first sentence, reference to parent application 09/157, 289, of which the current application is a continuation, is missing.

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#### *Claim Objections*

Claim 77 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It has the same limitations as claim 76 upon which it depends.

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#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67, 75 and dependent claims 68-74 and 76-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 67 and 75 are indefinite because of the recitation of “specifically binds”. Because specificity is dependent on binding conditions and is a relative term, it introduces ambiguity into the claim. Deletion of the term “specifically” could obviate this rejection.

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***Priority***

It is also noted that while provisional priority application 60/059,288 discloses the complete DcR3 protein and encoding nucleic acid sequences, it does not disclose a specific utility for the protein. It is disclosed only that the protein is related to TNFR2, but no specific ligand is identified and no actual antibody is taught. Therefore, the instant application is not granted benefit of priority to 60/059,288. For the sake of prior art, the effective filing date of the instant application is that of 60/094,640, filed 07/30/98.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 67-77 and 79-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Emery et al. (US Patent 5,885,800, cited by applicants) as evidenced by US Patent 4,946,778.

Emery et al. teach the TR4 polypeptide (SEQ ID NO:2) which has a sequence identical to the DcR3 polypeptide (SEQ ID NO:1) of the instant application. Also taught are antibodies that bind TR4, including antibody fragments, monoclonals, polyclonals, recombinant, and humanized antibodies, as well as methods of making the antibodies and antibody-producing host cells (col. 10, line 58 to col. 11, line 28). Uses for such antibodies are listed and include affinity chromatography of TR4, treatment of TR4 related diseases including cancer. TR4 is disclosed as

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structurally related to tumor necrosis factor (TNF) receptors (*e.g.*, col. 6, lines 42-61) for which ligands, including FasL (Fas ligand) are known (col. 1, lines 31-40). The methods of making single chain recombinant antibodies are cited as disclosed in US Patent 4,946,778, cited in col. 11, line 13. Also disclosed are TR4 polypeptide antagonists which are antibodies (col. 13, lines 22-23), which necessary include antibodies that block the binding of TR4 with its ligands. Such blocking includes binding of TR4 with not only Fas ligand, but also inherently LIGHT, absent evidence to the contrary.

The disclosure of US Patent 4,946,778 includes techniques for production in *E. coli*, (*e.g.*, col. 35, lines 44-47) as well as yeast and mammalian host cells (col. 11, lines 12-18), and is provided as evidence of what is disclosed and is not necessary for anticipation of the claimed invention.

### ***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 98/30694 (#35 cited by applicants) discloses TNFR-6 $\alpha$ , which has the same sequence as DcR3 of the instant application and is cumulative with the reference cited above.

The art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 99/14330 (#54) is not prior art, but issued from a PCT claiming priority to the two provisional applications to which the instant US application claims priority. Yu et al. (#213, J. Biol. Chem., 274(20): 13733-13736, May 1999) is not prior art, but teaches binding of DcR3 (called TR6) to FasL and LIGHT. It is suggested that "They may have a similar binding epitope for TR6 binding."

### ***Term Usage***

It is noted that the art also refers to DcR3 as TR4, TR6, TNFR-6 $\alpha$ , ZTNFR-5, human NTR-1, OPG-2, FLINT#1 and hAPO6.

### ***Conclusion***

Claims 30-39 and 85-89 are allowable.

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Claim 78 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

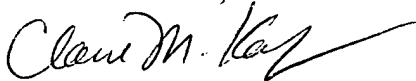
5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

20 Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

September 20, 2002